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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,030	06/29/2006	Krishna Murthy Ella	06-40104-US	7696
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REED SMITH LLP 2500 ONE LIBERTY PLACE 1650 MARKET STREET PHILADELPHIA, PA 19103			EXAMINER BLUMEL, BENJAMIN P	
			ART UNIT	PAPER NUMBER
			1648	
			MAIL DATE	DELIVERY MODE
			04/14/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/585,030

**Applicant(s)**

ELLA ET AL.

**Examiner**

BENJAMIN P. BLUMEL

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 10, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

***Election/Restrictions***

Applicant's election with traverse of required species (Hepatitis B antigen) in the reply filed on December 14, 2009 is acknowledged. The traversal is on the ground(s) that the species election of a specific protein from claim 18 is not supported by prior art to establish that the invention of claims 1, 2, 16 and 18 has a lack of unity, which has to be shown in order to separate claimed features of an invention. In addition, the Examiner has not shown that the species of claim 18 do not relate to a single general inventive concept and that the examiner must establish why there is a serious search burden if all the claimed species were examined. This is not found persuasive because while the claimed method involving HIMAX (claim 1) hasn't changed as a result of claim 18, the different proteins of claim 18 are from different pathogens: Rabies antigen (enveloped virus of the *Rhabdoviridae* family), Hepatitis A antigen (non-enveloped virus of the *Picornaviridae* family), Hepatitis B antigen (enveloped virus of the *Hepadnaviridae* family), Diphtheria toxoid (from *C. diphtheriae*-gram positive bacteria) and Tetanus toxoid (from *C. tetani*-gram positive bacteria). Therefore, searching the claimed method based on one of these antigens would not encompass the other claim antigens. Therefore, the species lack the same special technical features and a serious search burden does exist in searching the claimed method with regard to more than one of these species.

The requirement is still deemed proper and is therefore made FINAL.

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This application contains claims 10, 12 and 13 are drawn to species nonelected with traverse in the reply filed on June 13, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-9, 11 and 14-18 are examined on the merits.

***Response to Arguments***

Applicant's arguments with respect to claims 1-9, 11 and 14-17 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**(New Rejection Necessitated by Amendments)**

Claims 1-9, 11, 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

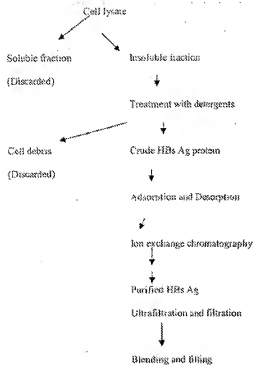
Claims 1 and 3 recite, "A process for the preparation and purification of protein(s) using Hydrophobic Interaction Matrix (HIMAX) technology comprising:...", however, it is unclear if applicants are referring to the combination of steps (a)-(h) of claim 1 and steps (a)-(c) of claim 3 as the "HIMAX technology" or if a specific step(s) among these is the actual HIMAX technology. This is unclear since the specification states on page 5 that HIMAX method uses certain ionic salts and buffers for capturing the produced protein(s) and multiple flow charts indicate different associations between HIMAX and protein production/purification.

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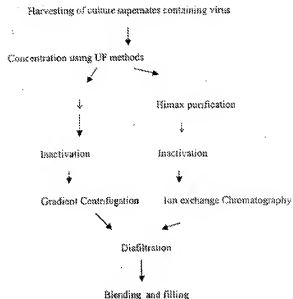
**Flow Chart for HBs Ag production using HIMAX**

Large Scale Fermentation

Cell Harvest and Lysis

**Flow chart for HIMAX in Rabies Vaccine production**

Large scale virus culture



For example, the HBsAg flow chart and the Rabies vaccine flow chart refer to HIMAX in different ways (i.e., one is the entire process [HBsAg] and in the other, HIMAX is a specific step in the process [Rabies Vaccine]).

Claim 1 recites, "...subjecting the insoluble matrix to centrifugation optimally to form a pellet...", however, it is unclear what the metes and bounds of "centrifugation optimally" are.

Claim 1 recites, "...(g)...pellet from step (f) to a repeated desorption process...", however, claim 1 does not recite that a desorption process was performed prior to step

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(g). Therefore, it is unclear if repeated desorption step is referring to a previous step of the method or that the procedure of step (g) implies that the desorption is repeatable.

Claim 3 recites, "...Tris base salts of high basicity.", however, it is unclear if "high" basicity is a Tris base salt of a pH of 14, 13, 11, 9 or 8.

Claim 5 recites, "The process of claim 4 wherein the viral antigen is inactivated before said desorption process.", however, since claim 4 establishes that the viral antigen is a protein, it is unclear how this viral antigen "protein" can be inactivated when it does not possess any activity unless part of the virus that it is derived from. A similar issue resides in claim 7.

Claim 6 recites, "The process of claim 5, wherein said protein is one other than a viral antigen", however, since claims 4 and 5 establish that the viral antigen is a protein, it is unclear how the claimed viral antigen can not be a protein.

Claim 7 recites, "...wherein said inactivation step is avoided before desorption.", however, claim 5 recites, "...is inactivated before said desorption process." Therefore, it is unclear whether or not an inactivating step does take place before desorption.

Claim 11 recites, "...claim 3, wherein the detergent is not used for the preparation and purification of protein(s).", however, the only recitation in claim 3 of detergent is specific for step (d). Therefore, does claim 11 now require that no detergent is used throughout the entire procedure of claim 3 or in specific steps since claim 11 recites, "...the detergent..."

Claim 15 recites, "...do not interfere with/affect the process of preparation...", however, it is unclear what the metes and bounds of "affect" are.

***Claim Objections***

**(New Objection Necessitated by Amendments)**

Claims 1 and 3 are objected to because of the following informalities: each claim recites, "...pH 6 to 7. 5..." It is therefore suggested that applicants amend the claim to recite, "...pH 6 to 7.5...". Appropriate correction is required.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/  
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/  
Examiner  
Art Unit 1648